

Message Text

UNCLASSIFIED

PAGE 01 STATE 168680
ORIGIN COME-00

INFO OCT-01 EA-12 ISO-00 EB-08 SS-15 STR-07 TRSE-00
AGR-01 JUSE-00 L-03 CIAE-00 INR-10 NSAE-00 OES-07
HEW-06 /070 R

DRAFTED BY COM/BIEPR/OCA/JPN/TFC:F J KLINE:EH
APPROVED BY EA/J:N PLATT
COM/BIEPR/OCA/JPN:C JOHNSON
COM/BIEPR/OCA/JPN/TFC:N GLICK
COM/ITA/AGC:S ELLIS
STATE/EA/EP:D STEBBING
DESIRED DISTRIBUTION
E, EA, EB, COMMERCE, STR, TREASURY, USDA, JUSTICE
-----014962 040126Z /64
P 032351Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 168680

E.O. 11652: N/A

TAGS: ETRD, JA

SUBJECT: TRADE FACILITATION COMMITTEE CASE - CONCEPT INC.

REF: (A) TOKYO 10653; (B) STATE 135658

1. SUMMARY. USDOC FORWARDING REVISED CASE FOR SUBMISSION TO TFC ON BEHALF OF CONCEPT. CASE BASED ON INFORMATION PROVIDED BY EMBASSY FOLLOWING DISCUSSIONS WITH MINISTRY OF HEALTH AND WELFARE (MHW), FURTHER COMMERCE (USDOC) DISCUSSIONS WITH CONCEPT INC., AND CONSULTATION WITH US FEDERAL DRUG ADMINISTRATION (FDA). END SUMMARY.

2. CONCEPT INITIALLY CONTACTED USDOC IN APRIL CONCERNING UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 168680

THIS MARKET ACCESS PROBLEM RESULTING FROM MHW REGULATIONS RELATED TO TRANSFER OF PRODUCT APPROVAL TO A NEW AGENT (REFTEL B). EMBASSY AFTER CONSULTATION WITH MHW, REPORTED (REFTEL A) THAT GOJ REGULATIONS GAVE ORIGINAL AGENT PROPRIETARY RIGHTS TO PRODUCT TEST DATA AND IT WAS UP TO GOOD WILL OF AGENT TO PROVIDE DATA TO NEW AGENT. USDOC BELIEVES THIS CASE WARRANTS TFC CONSIDERATION SINCE

THE FORMER AGENT NOT FORTHCOMING IN PROVIDING TEST DATA, AND IN BROADER TERMS TO ESTABLISH THE PROPRIETARY RIGHTS OF AMERICAN PRINCIPALS TO THE APPROVAL OF THEIR PRODUCTS FOR MARKETING IN JAPAN, CONSISTENT WITH US PRACTICES.

3. TEXT OF TFC CASE ON BEHALF OF CONCEPT INC. TO BE PRESENTED TO GOJ ALONG FOLLOWING LINES:

A. SUMMARY OF CASE: CONCEPT INC. (CONCEPT) IS A US MANUFACTURER AND EXPORTER OF MEDICAL EQUIPMENT TO JAPAN. THE MINISTRY OF HEALTH AND WELFARE (MHW) REQUIREMENT THAT THE FIRM'S PRODUCT, "PRESSURE-VEIL" -- A DISPOSABLE BLOOD PRESSURE MONITORING DEVICE, BE RETESTED AND REINSPECTED FOLLOWING APPOINTMENT OF A NEW JAPANESE AGENT WILL FURTHER DELAY INTRODUCTION OF THIS PRODUCT IN JAPAN.

B. FACTS OF THE CASE: CONCEPT, A FLORIDA-BASED MANUFACTURER OF MEDICAL AND HEALTH CARE EQUIPMENT, HAS BEEN SUCCESSFULLY MARKETING ITS LINE OF EQUIPMENT, INSTRUMENTS AND SUPPLIES IN JAPAN THROUGH SEVERAL AGENTS AND DISTRIBUTORS FOR ABOUT EIGHT YEARS. IN JANUARY 1975 CONCEPT APPOINTED AMERICAN COMMERCIAL CO. OF TOKYO (AMCO) AS ITS

EXCLUSIVE AGENT IN JAPAN FOR THE SALES OF ITS "PRESSURE-VEIL" DISPOSABLE BLOOD PRESSURE MONITORING DEVICE, USED IN ANAESTHESIOLOGY. IN ACCORDANCE WITH THE PHARMACEUTICAL UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 168680

AFFAIRS LAW (PAL) OF 1960, AS AMENDED, AMCO APPLIED FOR THE NECESSARY PRODUCT APPROVAL AND APPROVAL TO ACT AS IMPORTER AND DISTRIBUTOR OF THE PRODUCT. ALTHOUGH PROCESSING OF THE APPLICATION FOR APPROVAL BEGAN IN EARLY 1975, IT WAS NECESSARY TO REINITIATE TESTING JUNE 1975 FOLLOWING CHANGES IN PRODUCT PACKAGING. AMCO RECEIVED APPROVAL FOR THE IMPORTATION AND DISTRIBUTION OF THE PRODUCT AND IN MAY 1977, APPROVAL OF "PRESSUREVEIL" WAS GRANTED. AMCO'S AGENCY WAS TERMINATED BY MUTUAL AGREEMENT IN JULY 1977 FOR BUSINESS REASONS.

CONCEPT HAS SUBSEQUENTLY APPOINTED KESEI MEDICAL INDUSTRIAL

CO., LTD., OF TOKYO AS ITS NEW EXCLUSIVE AGENT. KESEI WAS ADVISED THAT UNLESS DUPLICATE TEST DATA COULD BE OBTAINED FROM THE FORMER AGENT, AMCO, THE PRODUCT WOULD HAVE TO BE RETESTED IN CONNECTION WITH OBTAINING THE NECESSARY APPROVALS TO IMPORT AND DISTRIBUTE THE PRODUCT, ALTHOUGH "PRESSUREVEIL" HAD ALREADY UNDERGONE THE NECESSARY CLINICAL TESTING AND DESIGN INSPECTION PRIOR TO GRANTING THE APPROVAL TO AMCO IN MAY 1977. CONCEPT IS PROVIDING KESEI WITH THE NECESSARY DESIGN AND TECHNICAL DATA, AND PRODUCT

SAMPLES TO INITIATE THE REQUIRED RETESTING; HOWEVER, THE REQUIREMENT TO RETEST THE SAME PRODUCT WILL FURTHER DELAY CONCEPT'S INTRODUCTION OF THE PRODUCT IN JAPAN.

C. DISCUSSION: THE MHW REQUIREMENT THAT A PRODUCT PRE-

VIOUSLY APPROVED MUST BE RETESTED IS CLEARLY A BURDENSOME IMPEDIMENT TO THE INTRODUCTION OF THAT PRODUCT INTO JAPAN. "PRESSUREVEIL" IS CURRENTLY IN WIDESPREAD USE IN THE UNITED STATES AND IN OTHER DEVELOPED COUNTRIES. IT WAS TESTED AND APPROVED BY THE MHW A YEAR AGO. JAPANESE GOVERNMENT REGULATIONS WHICH PROHIBIT ACCESS BY CONCEPT INC. AND ITS CURRENT EXCLUSIVE AGENT IN JAPAN, KESEI MEDICAL INDUSTRIAL CO., LTD. TO TEST DATA POSSESSED BY THE MHW RELATED TO UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 168680

APPROVAL OF "PRESSUREVEIL", A PRODUCT MANUFACTURED BY

CONCEPT, CLEARLY DENY THE LEGITIMATE PROPRIETARY INTEREST POSSESSED IN THE PRODUCT AS ITS MANUFACTURER. CONCEPT'S PROPRIETARY INTEREST CLEARLY EXTENDS TO KESEI MEDICAL INDUSTRIAL CO. AS ITS CURRENT LEGAL AGENT IN JAPAN.

SINCE JAPANESE REGULATIONS DO NOT PROVIDE FOR THE REGIS-

TRATION OF US MANUFACTURERS, BUT REQUIRE THEM TO ACT THROUGH A JAPANESE FIRM, THEY ARE PLACED IN THE POSITION OF BEING DEPENDENT UPON THE "GOOD WILL" OF SUCH A FIRM IN CASES WHERE THEY DETERMINE THAT TRANSFER OF THE AGENCY IS IN THEIR BEST BUSINESS INTEREST. THE BURDENSOME NATURE OF THIS IS CLEAR IN THIS CASE. AMCO, THE FORMER AGENT, HAS NOT BEEN PREPARED TO BE FORTHCOMING WITH SUCH "GOOD WILL".

WHILE IT IS UNDERSTOOD THAT THE INTENT OF THE JAPANESE REGULATIONS IS NOT TRADE RESTRICTIVE, AND THAT THEY ARE DESIGNED TO PROTECT THE HEALTH AND WELFARE OF THE JAPANESE PEOPLE BY INSURING THE EFFICACY AND SAFETY OF MEDICAL EQUIPMENT SOLD IN JAPAN THROUGH ESTABLISHING CONTROLS OVER ITS MANUFACTURE, IMPORTATION AND DISTRIBUTION, THE IMPACT OF THE PROVISIONS OF THE REGULATIONS WHICH ARE THE SUBJECT OF THIS CASE IS TO IMPEDE ACCESS TO THE JAPANESE MARKET BY US FIRMS.

JAPANESE PRACTICE WITH RESPECT TO US MANUFACTURERS OF MEDICAL EQUIPMENT DIFFERS MARKEDLY FROM THAT APPLIED TO JAPANESE AND OTHER FOREIGN MANUFACTURERS MARKETING MEDICAL EQUIPMENT IN THE US. FOREIGN MANUFACTURERS MAY MARKET THEIR PRODUCTS DIRECTLY IN THE US PROVIDED THEY COMPLY UNCLASSIFIED

UNCLASSIFIED

PAGE 05 STATE 168680

WITH ALL APPLICABLE LAWS AND REGULATIONS. FOREIGN MANUFACTURERS ARE AFFORDED THE OPPORTUNITY TO REGISTER AND OBTAIN NECESSARY APPROVALS FOR THEIR PRODUCTS UNDER SECTION 510 OF THE "FEDERAL FOOD, DRUG AND COSMETIC ACT AS AMENDED", ALONG WITH THEIR US AGENTS, SHOULD THEY

ELECT TO DISTRIBUTE THEIR PRODUCT THROUGH SUCH A FIRM. SECTIONS 520, 301 AND 707 OF THE ACT PROVIDE FOR PROTECTION OF THE CONFIDENTIALITY OF TRADE SECRET INCLUDED IN PRODUCT SPECIFICATIONS, TEST DATA AND OTHER INFORMATION SUBMITTED IN CONNECTION WITH NECESSARY APPROVALS. HOWEVER, THE MUTUAL PROPRIETARY INTEREST OF THE FOREIGN MANUFACTURER AND ITS LEGAL AGENT IN THE US IN SUCH CONFIDENTIAL INFORMATION IS CLEARLY ACKNOWLEDGED BY THE FDA.

D. RELIEF SOUGHT: THE US GOVERNMENT REQUESTS ON BEHALF OF CONCEPT THAT THE MHW ACCEPT THE RESULTS IN ITS FILES OF THE PREVIOUS TESTS OF "PRESSUREVEIL" CONDUCTED IN CONNECTION WITH THE GRANTING OF APPROVAL OF THE PRODUCT IN MAY 1977, AND THAT APPROVAL OF KESEI MEDICAL INDUSTRIAL EQUIPMENT CO., LTD., TO IMPORT AND DISTRIBUTE "PRESSUREVEIL" BE EXPEDITED.

THE US GOVERNMENT FURTHER REQUESTS THAT THE GOVERNMENT OF JAPAN ESTABLISH AND PROTECT THE PROPRIETARY INTEREST OF US MANUFACTURERS OF MEDICAL EQUIPMENT IN TEST AND OTHER DATA PROVIDED IN CONNECTION WITH MHW APPROVALS BY INCLUDING THE US MANUFACTURER AS A PARTY IN THE PRODUCT APPROVAL PROCESS. THIS WOULD PROVIDE THE US MANUFACTURER ACCESS TO NECESSARY INFORMATION IN MHW'S FILES SHOULD A TRANSFER OF AGENCY OCCUR.

3. ACTION REQUESTED: THE EMBASSY IS REQUESTED TO SUBMIT THE CASE TO THE TFC, TO CONTINUE ASSISTANCE TO CONCEPT AND ITS AGENT, KESEI MEDICAL INDUSTRIAL, AND TO UNDERTAKE ANY NECESSARY FURTHER CONSULTATIONS WITH MHW AND OTHER GOJ
UNCLASSIFIED

UNCLASSIFIED

PAGE 06 STATE 168680

AGENCIES RELATED TO THE CASE.

IN DISCUSSIONS WITH JAPANESE OFFICIALS EMBOFFS MAY EMPHASIZE THAT FDC POLICY WITH RESPECT TO MEDICAL DEVICE REGULATIONS IS TO PROVIDE EQUAL TREATMENT TO FOREIGN AND US MANUFACTURERS. IN ADDITION TO POINTS NOTED IN PARA 3.C OF CASE, EMBOFFS MAY WISH TO ALSO NOTE THE FOLLOWING. US

FDA OFFICIALS ARE PREPARED TO UNDERTAKE INSPECTIONS OF
REGISTERED FOREIGN MANUFACTURING FACILITIES WHICH MAY BE
REQUIRED PURSUANT TO SECTION 704 OF THE ACT. THE FDA
ACCEPTS VALID TEST DATA PERFORMED BY FOREIGN ORGANIZATIONS
WHICH IS SUBMITTED IN COMPLIANCE WITH CLASSIFICATIONS
(SEC 513), STANDARDS (SEC 514) AND PRE-MARKET APPROVAL
(SEC 515) PROCEDURES UNDER THE ACT. VANCE

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: TRADE AGREEMENTS, COMMITTEE MEETINGS
Control Number: n/a
Copy: SINGLE
Draft Date: 03 jul 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE168680
Document Source: CORE
Document Unique ID: 00
Drafter: F J KLINE:EH
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780274-0945
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780798/aaaadewy.tel
Line Count: 231
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: e7c27c7b-c288-dd11-92da-001cc4696bcc
Office: ORIGIN COME
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 5
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 78 TOKYO 10653, 78 STATE 135658
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2123699
Secure: OPEN
Status: NATIVE
Subject: TRADE FACILITATION COMMITTEE CASE - CONCEPT INC.
TAGS: ETRD, JA
To: TOKYO
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/e7c27c7b-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014